REMARKS

A. THE AMENDMENTS TO THE CLAIMS

Claims 1-17, 19-56, and 65-83 are pending. Claims 17, 39-56, and 65-83 are withdrawn from consideration, and claims 1-16 and 19-38 are currently under examination insofar as the claims read on a composition or a preparation comprising an antibody that binds to a peptide of NF-κB inducing kinase (NIK) set forth in SEQ ID NOs: 7, 11, or 12.

Claims 1, 19, and 30 have been amended to delete the phrase "or a portion of said amino acid sequence" and to delete reference to SEQ ID NOs: 2-6, 8-10, 13-20, and 22. Similarly, claim 17 was amended to delete reference to SEQ ID NOs: 2-6, 8-10, 13-20, and 22. Claim 14 was amended to delete the phrases "mutein, functional derivative, active fraction, circularly permutated derivative or salt thereof" and "or a portion of said amino acid sequence." Claims 2, 10, and 31 were canceled. No new matter has been added by way of the amendments.

B. THE OFFICE ACTION

Claims 1-16 and 19-38 were rejected under 35 U.S.C. § 112, first paragraph, for assertedly lacking enablement. Claims 1-16 and 19-38 were rejected under 35 U.S.C. § 112, first paragraph, for assertedly lacking written description. The Office rejected claims 1-16 and 30-38 under 35 U.S.C. § 102(e) for assertedly being anticipated by U.S. Patent No. 6,822,138 ("Schreiber").

C. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (ENABLEMENT), SHOULD BE WITHDRAWN.

Claims 1-16 and 19-38 were rejected under Section 112, first paragraph, for assertedly lacking enablement. Reconsideration of the rejection is respectfully requested in view of the amendments to the claims and the reasons set forth below.

The Office maintained the rejection of claims 1-16 and 19-38 because the specification assertedly does not enable the making or using of an antibody that binds to "any" amino acid or portion of SEQ ID NOs: 7, 11, and 12 while retaining the ability to

detect NIK or a mutein, functional derivative, active fraction, circularly permutated derivative, salt, or a portion of NIK. In particular, the Office asserted that the claims encompass antibodies that bind to as few as two amino acids of SEQ ID NOs: 7, 11, and 12 and variants of SEQ ID NOs: 7, 11, and 12, while only antibodies that bind to the amino acid sequences set forth in SEQ ID NOs: 7, 11, and 12 have been disclosed.

While Applicants disagree with the Office's assertions, solely in an effort to advance prosecution of the instant application, the claims have been amended to delete reference to SEQ ID NOs: 1-6, 8-10, 13-20, and 22, to delete the phrase "or a portion of said amino acid sequence," and to delete the phrase "mutein, functional derivative, active fraction, circularly permutated derivative, or salt thereof." The Office acknowledged that the specification fully enables the anti-NIK antibodies or fragments thereof that bind the amino acid sequence set forth in SEQ ID NOs: 7, 11, and 12. Office Action, p. 3. Thus, the rejection of claims 1, 3-9, 11-16, 19-30, and 32-38 under 35 U.S.C. § 112, first paragraph, has been rendered moot and should be withdrawn.

D. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (WRITTEN DESCRIPTION), SHOULD BE WITHDRAWN.

Claims 1-16 and 19-38 were rejected under Section 112, first paragraph, for assertedly lacking written description. Reconsideration of the rejection is respectfully requested in view of the amendments to the claims and the reasons set forth below.

The Office asserted that the specification "does not appear to provide an adequate written description for the all various portions of SEQ ID NO: 7, 11 or 12, and all muteins, functional derivatives, active fractions, circularly permutated derivatives, salts of NIK as targets of the claimed antibodies because there is lack of sufficient written description to support the recited genus of the antibody targets." Office Action, p. 6.

While Applicants disagree with the Office's assertions, the claims have been amended solely in an effort to advance prosecution of the instant application to delete reference to SEQ ID NOs: 1-6, 8-10, 13-20, and 22, and to delete the phrase "or a portion of said amino acid sequence." The Office acknowledged that the specification fully enables the anti-NIK antibodies or fragments thereof that bind the amino acid sequence set forth in SEQ

ID NOs: 7, 11, and 12. Office Action, p. 7 ("[o]ther than the antibody binding to the SEQ ID NO: 7, 11 or 12, there does not appear to be an actual reduction to practice. . . ."; emphasis added). Although there is no requirement to disclose an actual reduction to practice of any claimed subject matter in a patent application (to provide written description or for any other reason), the Office's implied recognition of the now-claimed subject matter as actually reduced to practice, and more importantly, as supported by a written description, is acknowledged. Thus, the rejection of claims 1, 3-16, 19-30, and 32-38 under 35 U.S.C. § 112, first paragraph, has been rendered moot and should be withdrawn.

E. THE REJECTION UNDER 35 U.S.C. § 102(e) SHOULD BE WITHDRAWN.

Claims 1-16 and 30-38 were rejected under 35 U.S.C. § 102(e) for assertedly being anticipated by Schreiber. The rejection is respectfully traversed for the reasons set forth below.

Schreiber anticipates the pending claims only if the reference teaches each and every element of the pending claims. See, e.g., *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631 (Fed. Cir. 1987). Claims 1, 3-16, 19-30, and 32-38 are directed to a preparation or pharmaceutical composition comprising one or more polyclonal, monoclonal, chimeric, humanized, human or anti-anti-idiotype antibodies and/or fragments thereof capable of specifically binding the amino acid sequence set forth in SEQ ID NOs: 7, 11, or 12. The referenced amino acid sequences are subregions or fragments of the NIK protein. Schreiber discloses a genus of antibodies that bind NIK, and does not teach each and every feature of the instant antibody or antibody fragment that selectively binds an amino acid sequence as recited in the pending claims. Disclosure of a genus does not anticipate a claimed species. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category"). Indeed, the reference does not teach or suggest the specific portion of NIK to which the claimed antibody binds, nor does the reference teach a subset of antibodies that specifically bind the recited NIK fragments.

The Office stated that "given that polyclonal antibodies are known to bind multiple epitopes on one antigen, the prior art polyclonal antibody raised against NIK would

necessarily bind to the epitopes comprising the amino acid sequences of SEQ ID NO: 7, 11 or 12." Office Action, p. 9. To rely on a theory of inherency, however, the Office must provide "a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Interf. 1990). "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations omitted). The Office failed to present evidence or reasoning showing that any prior art antibodies would necessarily bind to the portions of NIK recited in the claims and, therefore, has not met the Office's burden. Without such evidence or reasoning, the Office cannot require an applicant to prove that the prior art does not possess the claimed characteristic. M.P.E.P. § 2112(IV); See also *Ex parte Jurg Zimmerman* 2003 WL 25277881, *4 (Bd. Pat. App. & Interf. 2003); quoting *Ex parte Skinner*, 2 U.S.P.Q.2d 1788 (Bd. Pat. App. & Interf. 1986). Moreover, the assertion that the polyclonal antibody of Schreiber would necessarily bind to the epitopes comprising the amino acid sequences of SEQ ID NOs: 7, 11 or 12 is not scientifically accurate. Polyclonal antibodies are a combination of antibodies that specifically recognize a particular immunogen, which may contain one or more antigenic molecules. These antigens, in turn, may or may not include the same epitopes. Thus, it is not true that the polyclonal anti-NIK antibody of Schreiber would necessarily bind the epitopes (i.e., amino acid sequences set forth in SEQ ID NO: 7, 11, or 12) recited in the pending claims. A polyclonal antibody generated against a portion of a protein will only recognize epitopes within that portion. For example, a polyclonal antibody raised against SEQ ID NO: 7 (comprising amino acids 405-420 of NIK) would not necessarily bind residues 635-650 (SEQ ID NO: 11) of NIK. Even a polyclonal antibody generated against a whole protein may not recognize every epitope in the protein. Thus, it is untrue that the (prophetic) polyclonal antibody of Schreiber would necessarily bind the amino acid sequences of SEQ ID NOs: 7, 11, and/or 12 because the epitopes recognized by polyclonal antibodies generated against whole proteins are unpredictable. Additionally, the specification provides evidence that not all polyclonal anti-NIK antibodies detect NIK in a Western blot or immunoprecipitation assay. See Table 2 of the application-as-filed. As explained at page 73, lines 1-10, commercially available polyclonal antibodies raised against NIK either did not detect NIK or suffered from batch-to-batch variation. These disclosures directly refute the premise underlying the Office's

position (that all polyclonal antibodies bind all epitopes of the target) and establish that polyclonal antibodies do not inherently bind all such epitopes.

Moreover, the passages cited by the Office describe prophetic examples of antibodies. For example, Schreiber states that "[i]n numerous embodiments of the present invention, antibodies that specifically bind to NIK polypeptides will be used." See column 18, lines 41-43. Use of the future tense of the verb ("will be") indicates that the antibodies will be elicited in the future and do not exist currently. As such, it cannot be said that Schreiber's (prophetic) antibodies necessarily bind the epitopes comprising the amino acid sequences of SEQ ID NOs: 7, 11, or 12 because the passages cited by the Office do not describe any existing antibodies that can be tested to determine what epitopes are recognized. On a theoretical level, moreover, the prophetic polyclonal antibodies of Schreiber would not necessarily bind the claim-recited epitopes, as established in the preceding paragraph. Thus, the Office cannot rely on the doctrine of inherency to establish that Schreiber's antibody would necessarily bind SEQ ID NOs: 7, 11, or 12.

Applicants have shown that features of the claimed antibodies are not necessarily found in the genus of anti-NIK antibodies of Schreiber. The reference fails to explicitly or inherently disclose the particular anti-NIK antibodies of the pending claims. Therefore, the rejection of claims 1-16 and 30-38 under 35 U.S.C. § 102(e) over Schreiber has been overcome and should be withdrawn.

F. CONCLUSION

Applicants submit that the pending application is in condition for allowance. The Examiner is invited to contact the undersigned attorney by telephone if there are issues or questions concerning this submission that might be efficiently resolved in that manner.

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Respectfully submitted,

By 

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